IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKERMES PHARMA IRELAND LIMITED,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
INTELLIPHARMACEUTICS CORPORATION and INTELLIPHARMACEUTICS LTD.	)	
Defendants.	)	

COMPLAINT

Plaintiff Alkermes Pharma Ireland Limited ("Alkermes"), for its Complaint against Defendants IntelliPharmaCeutics Corporation ("IPC Corp.") and IntelliPharmaCeutics Ltd. ("IPC Ltd."), alleges as follows:

PARTIES

1. Alkermes is an Irish corporation having its principal place of business at Monksland, Athlone, County Westmeath, Ireland.

2. On information and belief, IPC Corp. is a Canadian corporation organized under the laws of Nova Scotia, having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC Corp. is the subsidiary and agent of IPC Ltd., and is developing generic drug products for sale and use throughout the United States, including this judicial district. On information and belief, IPC Corp. is controlled and/or dominated by IPC Ltd.

3. On information and belief, IPC Ltd. is a Delaware corporation having a principal place of business at 30 Worcester Road, Toronto, Ontario, Canada M9W 5X2. On information and belief, IPC Ltd. is developing generic drug products for sale and use throughout

the United States, including this judicial district. On information and belief, IPC Ltd. operates solely through its subsidiary and agent IPC Corp.

4. On information and belief, IPC Ltd. and IPC Corp. have common officers and directors and have represented to the public that they are a unitary entity. On information and belief, the acts of IPC Corp. complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of, and, in part, for the benefit of IPC Ltd. IPC Corp. and IPC Ltd. are hereinafter collectively referred to as "IPC."

NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 6,228,398 ("the '398 patent") and 6,730,325 ("the '325 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over IPC Corp. because, *inter alia*, of its presence in Delaware through IPC Ltd. and its continuous and systematic contacts with Delaware, including through IPC Ltd.

8. This Court has personal jurisdiction over IPC Ltd. because, *inter alia*, IPC Ltd. is a Delaware corporation and because of its continuous and systematic contacts within this judicial district.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

FACTUAL BACKGROUND

10. On May 8, 2001, the '398 patent, entitled "Multiparticulate Modified Release Composition," was duly and legally issued to Elan Corporation, plc ("Elan") as assignee. Elan's rights were subsequently transferred to Alkermes. A true and correct copy of the '398 patent is attached as Exhibit A.

11. On May 4, 2004, the '325 patent, entitled "Multiparticulate Modified Release Composition," was duly and legally issued to Elan as assignee. Elan's rights were subsequently transferred to Alkermes. A true and correct copy of the '325 patent is attached as Exhibit B.

12. On May 26, 2005, the United States Food And Drug Administration ("FDA") approved new drug application No. 21-802 for FOCALIN® XR capsules, which contain dexmethylphenidate hydrochloride, under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for the treatment of Attention Deficit Hyperactivity Disorder. The '398 and '325 patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for FOCALIN® XR capsules.

13. On information and belief, IPC submitted to the FDA abbreviated new drug application ("ANDA") No. 78-992 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of dexmethylphenidate hydrochloride extended release capsules in the 5, 10, 15, 20, 30, and 40 mg strengths, as generic versions of the FOCALIN® XR 5, 10, 15, 20, 30, and 40 mg capsules.

14. By letter dated May 16, 2012 (the "IPC Letter"), IPC advised Elan Pharma International Ltd. that it had submitted ANDA No. 78-992 seeking approval to manufacture, use,

or sell generic dexmethylphenidate hydrochloride extended release capsules in the 5, 10, 15, 20, 30, and 40 mg strengths prior to the expiration of the '398 and '325 patents.

15. Elan and IPC previously litigated the '398 and '325 patents with respect to IPC's ANDA No. 78-992 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules in the 5, 10, 15 and 20 mg strengths. That litigation was settled pursuant to a settlement agreement. *See Elan Corp., plc, et al. v. IntelliPharmaCeutics Corp, et al.*, C.A. No. 07-603-SLR (D. Del.).

16. Alkermes is currently litigating the '398 and '325 patents against IPC and Par Pharmaceutical, Inc. with respect to ANDA No. 78-992 seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules in the 30 mg strength. Alkermes' complaint in that action was filed on March 25, 2011. *See Alkermes Pharma Ireland Limited v. IntelliPharmaCeutics Corp., et al.*, C.A. No. 11-255-SLR (D. Del.).

17. Alkermes and IPC have not previously litigated the '398 and '325 patents with respect to IPC's ANDA seeking approval to manufacture, use, or sell generic dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength.

18. The IPC Letter also advised Elan that IPC's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in IPC's opinion, the claims of the '398 and '325 patents are invalid.

COUNT I

19. Alkermes incorporates each of the preceding paragraphs 1 to 18 as if fully set forth herein.

20. IPC's submission of ANDA No. 78-992 to the FDA for dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength, including the

§ 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '398 patent under 35 U.S.C. § 271(e)(2)(A). IPC's commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength would infringe the '398 patent.

21. On information and belief, IPC was aware of the existence of the '398 patent and was aware that the filing of ANDA No. 78-992 and certification with respect to the '398 patent constituted infringement of that patent. This is an exceptional case.

COUNT II

22. Alkermes incorporates each of the preceding paragraphs 1 to 21 as if fully set forth herein.

23. IPC's submission of ANDA No. 78-992 to the FDA for dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '325 patent under 35 U.S.C. § 271(e)(2)(A). IPC's commercial manufacture, offer for sale, or sale of the proposed generic for dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength would infringe the '325 patent.

24. On information and belief, IPC was aware of the existence of the '325 patent and was aware that the filing of ANDA No. 78-992 and certification with respect to the '325 patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Alkermes respectfully requests the following relief:

A. A judgment that IPC has infringed the '398 and '325 patents;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 78-992 for dexmethylphenidate hydrochloride extended release capsules in the 40 mg strength under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration dates of the '398 patent and '325 patent, including any extensions;

C. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining IPC, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from infringement of the '398 and '325 patents for the full terms thereof, including any extensions;

D. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

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